REMARKS

Reconsideration of this application in view of the following remarks is requested. After entry of this reply, claims 1-21 and 30-38 are pending in the application. In this Response and Amendment, claim 17 and 35 are amended. No claims are added or canceled. Claims 22-29 were previously canceled.

Please note and record our change of Attorney Docket Number in this matter to: 126066-00101. A Power of Attorney with Revocation will be shortly filed appointing Blank Rome LLP, One Logan Square, 130 North 18th Street, Philadelphia, PA 19103, having customer number 64574.

In the office action dated January 25, 2007, the Examiner rejects claims 1-16, 18-21 and 30-37 under 35 USC § 102(b) as anticipated by Ellinwood, Jr. (U.S. Patent No. 3,923,060); rejects claims 1-16, 18-21 and 30-37 under 35 USC § 102(e) as anticipated by Gelfand (US 2005/0192638); rejects claims 1-16, 18-21, 30-31 and 34-37 under 35 USC §103(a) as unpatentable over Klein et al. (Anesth Anal 2000; 91:1473-1478) in view of Xavier (U.S. Patent No. 5,458,631); and rejects claims 17 and 38 under 35 USC §103(a) as unpatentable over Ellinwood, Jr. (U.S. Patent No. 3,923,060) or Gelfand (US 2005/0192638) in view of Elkhoury (US Patent No. 5,919,473).

Claim Rejections – 35 USC § 102

Applicant respectfully traverses the Examiner's rejections of claims 1-16, 18-21 and 30-37 under: 1) 35 USC § 102(b) as anticipated by Ellinwood, Jr. (U.S. Patent No. 3,923,060); and 2)

under 35 USC § 102(e) as anticipated by Gelfand (US 2005/0192638). Neither Ellinwood nor Gelfand, alone, disclose each and every element of the claimed invention.

Ellinwood (U.S. Patent No. 3,923,060):

The Examiner states, at page 2 of the Office Action, that Ellinwood "discloses a method of providing long term management comprising...whereby pain management is provided for weeks, months, or years." Ellinwood does not disclose, teach or suggest long term pain management. Ellinwood is directed to treating hypertension, and is directed to dispensing medical substances to treat hypertension based upon determinations made by the dispensing device itself.

For example, the Summary of the Invention, at col. 2, lines 46-59, teaches a plurality of sensors, each adapted to sense a particular body condition at a particular point in the body, where the dispensing of medication is based upon changes in the sensed data. This arrangement of invention technique does not lend itself to pain management, and Ellinwood does not teach or suggest that pain management is included. Beginning at col. 3, line 68 through all of col. 6, Ellinwood's teachings are completely directed to treatment of malignant hypertension, and the sensing and treatment sites associated therewith. Even in col. 7, where other treatments are suggested (e.g., cancer by radio-active anti-cancer compounds dispensed based upon sensed concentrations; ulcers by anti-cholinergic drugs based upon sensed pH levels; epilepsy; spastic vascular disease; congestive cardiac failure and cardiac arthyumias), each treatment disclosed

involves specific site sensing and associated drug dispensing. Long term pain management is not included or contemplated in Ellinwood's teachings.

Further, while Ellinwood might teach peripheral neural structure sensing and medication delivery, Ellinwood does not disclose, teach or suggest the neural structure sites specifically recited in at least dependent claims 2, 5, 8, 9, 10, 11, 12, 13, 18, and 19 of the present application. Ellinwood also fails to disclose, teach or suggest medications selected from the group consisting of opiods, antispasmodics, alpha 2 agonists and local anesthetics, as specifically recited in at least claims 17, 35 and 38. In addition, Ellinwood fails to teach or suggest tetracaine, clonidine and baclofen, as specifically recited in at least claims 16 and 34.

Accordingly, considering that Ellinwood fails to disclose each and every element of the claimed invention, including at least the recitations of independent claims 1, 37 and 38, Applicant respectfully requests that the Examiner withdraw the 35 USC § 102(b) rejections based on Ellinwood.

Gelfand (US 2005/0192638):

Gelfand does not disclose each and every element of the claimed invention, as will be further explained. However, and in addition, Applicant submits that Gelfand (U.S. Patent Application Serial No. 2005/0192638) is not a prior art reference of the present application.

The Gelfand 2005/0192638 application was filed July 28, 2004. The 2005/0192638 application is a continuation-in-part of Application Serial No. 10/408,665 (now US 7,162,303), filed April 8, 2003, which claims benefit of priority of Provisional Application Serial Nos.: 1)

60/442,970, filed January 29, 2003; 2) 60/415,575, filed October 3, 2002; and 3) 60/370,190, filed April 8, 2002.

The present application (App'l Serial No. 10/616,247) was filed July 9, 2003, and claims benefit of priority to U.S. Provisional Application Serial No. 60/395,302, filed July 9, 2002. The claims at issue in the present application, to which the Examiner has cited the Gelfand 2005/0192638 application as a basis for rejection, are fully supported under 35 USC § 112, 1st paragraph, by U.S. Provisional Application Serial No. 60/395,302. Accordingly, only Gelfand's U.S. Provisional Application Serial No. 60/370,190, filed April 8, 2002, is a prior art reference.

Gelfand's U.S. Provisional Application Serial No. 60/370,190 is directed to infusion of a renal nerve to inhibit sympathetic neural stimulation of the kidney to treat congestive heart failure. All teachings of Gelfand are directed thereto. Even the Field of the Invention portion of U.S. Provisional Application Serial No. 60/370,190 specifically recites that the invention "relates to methods and apparatus for treatment of congestive heart failure (CHF). In particular, ... improvement of the condition of CHF patients by affecting their renal function by altering the neural control of the kidney."

Gelfand fails to disclose, teach or suggest long term pain management, or disclosure of any peripheral nerve except the renal nerve. Accordingly, Gelfand does not disclose, teach or suggest the neural structure sites specifically recited in at least dependent claims 2, 5, 8, 9, 10, 11, 12, 13, 18, and 19 of the present application. Gelfand also fails to disclose, teach or suggest medications selected from the group consisting of opiods, antispasmodics, alpha 2 agonists and

local anesthetics, as specifically recited in at least claims 17, 35 and 38. In addition, Gelfand fails to teach or suggest tetracaine, clonidine and baclofen, as specifically recited in at least claims 16 and 34.

Therefore, considering that Gelfand fails to disclose each and every element of the claimed invention, including at least the recitations of independent claims 1, 37 and 38, Applicant respectfully requests that the Examiner withdraw the 35 USC § 102(e) rejections based on Gelfand.

Claim Rejections – 35 USC § 103

The Examiner rejects claims 1-16, 18-21, 30-31 and 34-37 under 35 USC §103(a) as unpatentable over Klein et al. (Anesth Anal 2000; 91:1473-1478) in view of Xavier (U.S. Patent No. 5,458,631); and rejects claims 17 and 38 under 35 USC §103(a) as unpatentable over Ellinwood, Jr. (U.S. Patent No. 3,923,060) or Gelfand (US 2005/0192638) in view of Elkhoury (US Patent No. 5,919,473). Applicant respectfully traverses the Examiner's claim rejections under 35 U.S.C. §103(a), as Applicant denies that a prima facie case of obviousness has been established.

Klein et al. (Anesth Anal 2000; 91:1473-1478) in view of Xavier (U.S. Patent No. 5,458,631)

The Examiner states, at page 4 of the office action, that Klein discloses "a method of providing long term pain management that includes most of the limitations as recited in the claims...However, Klein teach[es] to use a disposable infusion pump to deliver the drugs instead of an implantable infusion pump." The Examiner continues: Xavier discloses an implantable

catheter and pump that provides long term pain management by infusing drugs into the epidural space of the patient. Accordingly, the Examiner believes it obvious to modify the method of Klein with the implantable pump of Xavier to make a method of establishing anesthesia for the surgery and post-operative periods that was less prone to complications such as overdosing. Applicant disagrees - modifying the method of Klein with the implantable pump of Xavier would not lead to the claimed invention.

To substantiate the combination of Klein and Xavier, the Examiner states that "Klein acknowledges that the results of his study demonstrate that it is possible to extend the duration of a peripheral nerve block by using a continuous infusion," in the first paragraph of the Discussion section of Klein. Applicant submits that Klein's statement was mis-interpreted by the Examiner. Klein specifically states, in the first paragraph of his Discussion section, that the results of his study "demonstrate that a small-dose continuous infusion of local anesthetic into the shoulder joint provides improved analgesia when compared with a brachial plexus block with long-acting amide local anesthetic alone." The comparison was specific, a small-dose continuous infusion of local anesthetic into the shoulder joint vs. brachial plexus block with long-acting amide local anesthetic alone. Further, Klein's results are only taken to 48 hours. Accordingly, interpretation of Klein's actual statement to infer demonstration of extension of the duration of a peripheral nerve block by using a continuous infusion is inaccurate, as it is adding meaning to the actual statement. Still further, Klein then proceeds, in his Discussion section, to discuss the difficulties associated with small-dose continuous infusion, suggesting that duration extension beyond the

time period considered (i.e., 12 to 48 hours) would be troublesome (see at least the last full paragraph of page 604).

The question raised under 35 U.S.C. §103 is whether the reference(s) taken as a whole would suggest the claimed invention taken as a whole to one of ordinary skill in the art. Accordingly, the claimed invention taken as a whole cannot be said to be obvious without some reason given in the reference(s) why one of ordinary skill would have been prompted to modify the teachings of the reference(s) to arrive at the claimed invention. Therefore, some reason or suggestion must be found in the evidence of record that would have led one of ordinary skill in the art to produce the claimed invention in order to properly establish a prima facie case of obviousness. Klein and Xavier fail to provide the reason or suggestion.

Klein discusses supplementing an operative interscalene brachial plexus block of 1.5% mepivacaine with a postoperative intraarticular infusion of 0.5% ropivacaine at 2ml/h. Klein's teaching of a postoperative intraarticular infusion is over a duration of, at most, 48 hours from the operative interscalene brachial plexus block. Klein assesses visual analog scale pain scores and postoperative oxycodone consumption over those 48 hours for those receiving the 0.5% ropivacaine intraarticular infusion versus those receiving a saline intraarticular infusion.

Klein concludes (beginning at the bottom of column one of page 604) that "the reduced pain provided by intraarticular ropivacaine infusion can be attributed to avoidance of the rapid resolution of neural blockade and sudden development of pain from a previously analgesic site." As Klein's intraarticular ropivacaine infusion is taught to bridge the "rapid resolution of neural

blockade," this conclusion teaches and suggests that Klein's method is directed to, and adequate for, only short term, acute postoperative pain, not for the long term, chronic pain management of the claimed invention.

An obviousness rejection under §103 requires that the surrounding circumstances or evidence of record make any proposed modification over the reference(s) obvious to *do* rather than obvious to *try*. The Examiner states that it would have been obvious to modify the method of Klein with the implantable pump of Xavier to make a method of establishing anesthesia for the surgery and post-operative periods that was less prone to complications such as overdosing. The Examiner makes this statement without any suggestion in Klein or Xavier that making the modification would result in the requisite expectation of success necessary to maintain a 35 U.S.C. §103 rejection.

The implanted catheter and pump of the present invention to deliver medications to a peripheral neural structure involve vastly different bodily spaces than the implanted catheter and pump of Xavier, and involve novel and different medicines, and different combinations of medicines, than the peripheral neural infusions of Klein. For example, nerve growth inhibiting medications of the present invention present half-life concerns differing from the disposable pump medication infusion of Klein, and the implantable pump medication infusions of Xavier. In addition, the nerve growth inhibiting medications require continuous use and fixed rate dosing concerns that Klein has not taught or suggested possible, that complicate an implanted system delivering to a neural structure, and perhaps explain why neither Klein nor Xavier suggest long

term implanted pump medication delivery to a peripheral neural structure. In addition, long term catheter access to the varying neural structures, and the design mechanics of the implanted components to deliver to the neural structures, differ vastly from the abdomen only implantation and solely epidural medication delivery of Xavier.

Therefore, the Examiner's statement of obviousness, without more, does not satisfy the burden of establishing a prima facie case of obviousness. One cannot base obviousness upon what a person skilled in the art might try or might find obvious to try but rather must consider what the reference(s) would have led a person skilled in the art to do successfully.

Furthermore, when evaluating a claim for obviousness, all limitations of the claim must be considered. Neither Xavier or Klein, either alone or in combination, disclose, teach or suggest an implanted catheter and pump, where the catheter discharges to a peripheral neural structure, and the pump operates to deliver continuous medication to the peripheral nerves, providing long term, chronic pain management.

Regarding exemplary dependent claims, even Klein's purported teachings of temporary medication delivery with a disposable pump to peripheral nerves, does not disclose or teach delivery to the peripheral nerves featured and recited in claims 8 through 13. Nor does Klein teach or suggest the doses featured and recited in claim 34.

For the foregoing reasons, applicant contends that a prima facie case of obviousness has not been established. Accordingly, the Examiner is respectfully requested to withdraw the §103(a) rejections based upon Klein in view of Xavier.

Ellinwood, Jr. (U.S. Patent No. 3,923,060) or Gelfand (US 2005/0192638) in view of Elkhoury (US Patent No. 5,919,473)

The Examiner states, at page 5 of the Office Action, that Ellinwood and Gelfand disclose a method that includes most of the limitations recited in claims 17 and 38, but fail to disclose delivering opiods or antispasmodics or alpha 2 agonists as the pain medication. The Examiner states that Elkhoury discloses that delivering opiods to peripheral nerves is effective in reducing pain.

In addition to a showing of: 1) suggestion or motivation to combine cited references; and 2) a reasonable expectation of success in combining the cited references; a rejection under §103 requires that the combined references teach all of the claim limitations. As detailed above in Remarks to the 35 USC § 102 rejections, neither Ellinwood nor Gelfand actually disclose the elements relied upon by the Examiner to substantiate to § 102 rejections, and therefore do not disclose the elements relied upon by the Examiner to substantiate the §103 rejections here for claims 17 and 38. Accordingly, neither Ellinwood and Elkhoury, nor Gelfand and Elkhoury, teach all of the claim limitations of claims 17 and 38.

Further, Elkhoury is directed to providing a method of relieving the pain of surgical wounds, preferably deep surgical wounds, and purportedly comprises placing an analgesic delivery device in the locality of the wound and delivering the analgesic directly to peripheral opioid receptors. Elkhoury teaches application of the analgesia by surgical suture, implant or externally-applied wound dressing. In all instances, Elkhoury envisions release of analgesia from a structural material, not through a catheter. There is no suggestion of delivery through a

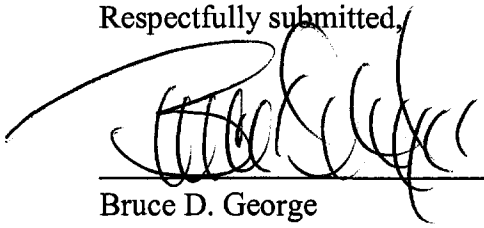
catheter. Accordingly, Elkhoury fails to provide the suggestion or motivation to combine its primarily externally applied analgesic, or subdermally applied analgesic released from a structural material (i.e., suture or implant), with the teachings of Ellinwood or Gelfand to create the claimed invention of the present application. Further, the duration of pain management in Elkhoury is only on the order of one to two days.

Lastly, the specific antispasmodic and alpha 2 agonist medications recited in claims 17 and 35, as amended, are not disclosed, taught or suggested (and have not even been characterized by the Examiner as disclosed, taught or suggested) in Elkhoury, Ellinwood, Gelfand, Klein, or Xavier, either alone or in any envisioned combination.

CONCLUSION

In light of the above amendments and remarks, Applicant submits that pending claims 1-21 and 30-38 are allowable, and requests that the Examiner issue an early notice of allowance. The Examiner is invited to call the undersigned attorney in the event that a telephone interview will advance prosecution of this application.

Respectfully submitted,



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